AUG 13 2008

Attachment II 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The Assigned 510(k) Number is: K073432

1. Applicant Device Information

Trade/Proprietary Name: Trauson Bone Plate
Common Name: Single/multiple component metallic bone fixation appliances and accessories
Classification Name: Plate, fixation, bone
Device Class: II
Product Code: HRS
Regulation Number: 888.3030
Review Panel: Orthopedic
Intended Use:
Trauson Bone Plate is intended for the fixation of fractures of humerus.

2. Submitter Information

Establishment Registration Name:
TRAUSON (JIANGSU) MEDICAL INSTRUMENT CO., LTD.
31 Houcun Road, Niutang Town
Changzhou, Jiangsu
CHINA 213163
Phone: +86-757-86280075
Fax: +86-757-86397179

Contact Person of the Submission:
Ms. Diana. Hong, Mr. Eric. Chen
Shanghai Mid-link Consulting Co., Ltd.
Suite 8D, No.19, Lane 999, Zhongshan No.2 Road(S)
Shanghai, 200030, CHINA
Phone: +86-21-64264467 x 152
Fax: +86-21-64264468 x 809
Email: Diana.hong@mid-link.net
Please CC: Eric.chen@mid-link.net

3. Predicate Device

K Number: K041965

Trade Name: ARTHREX HUMERAL FRACTURE PLATES AND SCREWS

4. Device Description

The applicant device of Trauson Bone Plate made of medic 11 grade 3 16L stainless steel that meet ASTM F138 is intended for the fixation of fractures of humerus. The plates vary essentially through different lengths, number of plate holes.

The applicant devices are not sterile. The materials are wildly used in the industry with well know biocompatibility. No new materials are used in the development of this implant. No surface modified or coated.

5. Test Data

Bench tests of the applicant device following ASTM F382 and ASTM F897 are conducted to determine the mean bending proof load and run-out load, please see the **Appendix 2**, ASTM Test Report

6. Substantially Equivalence

The applicant device is **Substantially Equivalent (SE)** to the predicate device in terms of Effectiveness and Safety.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Trauson (Jiangsu) Medical Instrument Co., Ltd.
% Shanghai Midlink Business Consulting Co., Ltd.
Ms. Diana Hong
Suite 8D, Zhongxin Zhongshan Mansion
No. 19, Lane 999, Zhong Shan No.2 Road
Shanghai, 200030, China

AUG 13 2008

Re: K073432
Trade/Device Name: Trauson Bone Plate
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS
Dated: July 29, 2008
Received: July 29, 2008

Dear Ms. Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

 K073432 (pg 1/1)

Attachment III Indications for Use

510(k) Number: K073432
Device Name: Trauson Bone Plate

Indications for Use:

Trauson Bone Plate is intended for the fixation of fractures of humerus.

Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchman for MPM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K073432